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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,078	03/01/2000	Zsolt Istvan Hertelendy, Pharm.D.,Ph.D	45061-8	3549

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/516,078

Applicant(s)

HERTELENDY, PHARM.D.,PH.D
ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,12,13 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,12,13 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-6, 8-11, 14-17 and 19-20 have been canceled.
2. Claims 7, 12-13 and 18 have been amended.

Interview Summary

3. An interview was conducted with Mr. Charles A. Crehore, Registration Number 27, 628 on May 27, 2004 in an effort to place the instant Application in condition for allowance. The examiner requested the cancellation of the species of invention not previously indicated as allowable over the prior art of record, in light of the amended claimed claims now reciting a non-allowable species of invention. Applicant requested a Final Office action over the amended claims.

Allowable Subject Matter Withdrawn

4. Claim 7, 12-13 and 18 have been amended to recite a species of invention previously rejected and not indicated as allowable, therefore Applicant's pending claims are no longer allowable and the submitted amendment necessitating new grounds of rejection over claims previously indicated as containing allowable subject matter.
5. It was the hope of the examiner that the previously indicated allowable subject matter would have been submitted in independent form, with the rejected subject matter deleted, but suppositories that comprise polyethylene glycol, for which prior art rejections had been made of record, were incorporated into claims 7, 12-13 and 18, thus necessitating new grounds of rejection over these claims.

Rejections Withdrawn

6. Claims 1-13, 17-20 rejected under 35 U.S.C. 112, first paragraph (scope of enablement), has been obviated through amendment of the claims to be directed to compositions for the induction of an immune response.

Rejection Maintained

7. Claims 7, 12-13 and 18 are rejected, as previously applied to claims 1-6, 10-11 and 17 (suppository compositions of polyethylene glycol and an antigen) under 35 U.S.C. 103(a) as being unpatentable over Beck et al (US Pat. 4,756,907) in view of Singh (US Pat. 5,858,371) for reasons of record in paper number 3, paragraph 15 and paper number 20, p 8 and 14-17.

8. Claim 18 is rejected, as previously applied to claims 17 and (method of inducing an immune response with a suppository composition of polyethylene glycol and an antigen) under 35 U.S.C. 103(a) as being unpatentable over Beck et al (US Pat. 4,756,907) in view of Azria (US Pat.) for reasons of record in paper number 3, paragraph 16 and paper number 20, paragraphs 9 and 18-21.

9. Claim 18 is rejected, as previously applied to claims 17, 19 and 20 (method of inducing an immune response with a suppository composition of polyethylene glycol and an antigen) under 35 U.S.C. 103(a) as being unpatentable over Beck et al (US Pat. 4,756,907) in view of Mizuna (US Pat. 4,462,984) for reasons of record in paper number 3, paragraph 17 and paper number 20, paragraphs 10 and 22-23.

10. Claims 7, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (US Pat. 5,783,194) as evidenced by US 20020034498, for reasons of record in paper number 20, paragraph 24.

11. Claims 7, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rovinski et al (WO98/44788) as evidenced by US 20020034498, for reasons of record in paper number 20, paragraph 25.

12. Claims 7, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Lingwood (US Pat. 6,218,147) as evidenced by US 20020034498, for reasons of record in paper number 20, paragraph 26.

13. Claims 7, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Melman (US Pat. 5,853,767) as evidenced by either Kondo (US Pat. 4,221,705) or Konishi et al (US Pat. 4,360,593), for reasons of record in paper number 20, paragraph 27.

Response to Arguments

14. Applicant's arguments filed March 16, 2004 have been fully considered but they are not persuasive.

15. Applicant did not address any of the references applied against the claims which recited the polyethylene glycol suppository and an immunogen as defined in paragraph (a) of newly amended claims 7, 12-13 and 18. Therefore, the prior art rejections applied against this embodiment of invention is maintained for reasons of record.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

17. Carey et al (US Pat. 4,746,508) is cited to show a method of vaccinating with a suppository that comprises a peptide antigen (see claims 60 and 71; col. 9, lines 43-50, lines 65-68 and col. 10, lines 1-6).

18. Eley (US Pat. 6,200,590) is cited to show a polyethylene glycol suppository for delivery of drug laden nanoparticles (see claims 1, 6-7).

19. Herschler (US Pat. 3,711,602; issue date 1973) is cited to show suppositories as carrier for antigens (see claims 3 and 6).

20. Neway et al (US Pat. 5,336,666) is cited to show a bacterial adjuvant in a suppository formulation (see abstract and claims 1 and 9).

21. Segev (US Pat. 5,908,845; issue date June 1, 1999; filing date October 30, 1996) and (US Pat. 6,348,583, effective filing date August 20, 1999) are cited to show polyethylene glycol suppositories that comprise anti-sense RNA and DNA of HIV (viral fraction) for induction of an immune response (see '845: col. 17, lines 45-54; col. 19, lines 32-52, especially lines 32-33 and 50-52 and all claims.) and (see '583: col. 25, lines 36-45 (pathogens both viral and *Candida albicans*); and col. 27, lines 35-55 (Peg suppositories)).

22. Rothbard et al (US Pat. 6,306,993; issue date October 23, 2001, effective filing date May 21, 1997) and (US Pat. 6,669,951, issue date Dec. 2003; effective filing date August 1999) are cited to show polyethylene glycol suppositories that comprise anti-sense oligonucleotides from HIV (see '993: col. 17, lines 32-41 and col. 21, lines 47-51 and lines 9-24; Example 3).

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

28. Vgp
29. June 14, 2004


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